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मानक

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IS 15735 (2006): Herbal cosmetics - General guidelines [PCD 19: Cosmetics]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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भारतीय मानक
हर्बल सौंदर्य प्रसाधन — सामान्य मार्गदर्शी सिद्धान्त

Indian Standard
HERBAL COSMETICS — GENERAL GUIDELINES

ICS 71.100.70

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BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Cosmetics Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

The awareness and need for cosmetics with herbs is on the rise, primarily because consumer believes that these products are safe and free from side effects. There is a need to provide assurance to the consumers that such products generally claimed and/or labelled to as 'Herbal Cosmetics' are actually delivering the benefit claims, safe and are of standard quality and provide the 'claimed cosmetic benefits' accruing from their use. There is a need for adoption of general guidelines by the formulators and marketers of such cosmetics.

Cosmetics claimed and labelled as 'Herbal' could be those products which are formulated using standard, approved cosmetic base into which herbs are added for providing the claimed product benefits. These guidelines address identified areas, which the formulators/marketers of herbal cosmetics need to comply. Formulators/Marketers who claim their cosmetic product to be a herbal cosmetic by labelling them with such words on the pack need to comply with the general guidelines for herbal cosmetics.

Formulators/Marketers can use herbs/herbal ingredients, for example, to create variants, in which case the cosmetic formulation shall be governed by the current regulations under the *Drugs and Cosmetics Act* and Rules as may be applicable, and this general guidelines for herbal cosmetics shall not be applicable to such products.

No stipulations have been made in these guidelines regarding the composition of the herbal cosmetics. However, it is necessary that the raw materials used in these formulations are such that in the concentrations in which they would be present in the finished cosmetics, after interaction with the other raw materials used in the formulation, are free from any harmful effects. For determining the suitability of a new formulation or of a new raw material used in an old formulation, reference may be made to IS 4011 : 1997 'Methods of test for safety evaluation of cosmetics (*second revision*)'. It shall be the responsibility of the manufacturers of finished cosmetic, to satisfy themselves of the dermatological safety of their formulation according to that standard before releasing the product for sale.

Indian Standard

HERBAL COSMETICS — GENERAL GUIDELINES

1 SCOPE

This standard primarily deals with general guidelines for herbal cosmetics.

2 REFERENCES

The following standards contain provisions, which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS No.	Title
3958:1984	Methods of sampling cosmetics (<i>first revision</i>)
4011:1997	Methods of test for safety evaluation of cosmetics (<i>second revision</i>)
4707	Classification of cosmetic raw materials and adjuncts:
(Part 1):2001	Dyes, colours and pigments (<i>second revision</i>)
(Part 2):2001	List of raw materials generally not recognized as safe for use in cosmetics (<i>second revision</i>)
11377:2001	Guidelines for hygienic manufacture of cosmetics (<i>first revision</i>)
14648:2005	Methods of test for microbiological examination of cosmetics and cosmetic raw materials (<i>first revision</i>)

3 DEFINITIONS

3.1 Herbal Cosmetics — Herbal cosmetics, hereinafter referred as products are formulated, using various permissible cosmetic ingredients [see IS 4707 (Part 1) and IS 4707 (Part 2)] to form the base in which one or more herb(s)/herbal ingredient are used to provide defined cosmetic benefits with a label declaration as 'Herbal Cosmetic'. These Guidelines shall be applicable where the term 'Herbal Cosmetics' are declared in the PCRO (as per the Packaged Commodities Regulation Order) panel.

NOTE — Such Products should comply with the definition of Cosmetics as defined in the *Drugs & Cosmetics Act* and also comply with Schedule S of the *Drugs & Cosmetics Rules, 1945*. Finished cosmetics for which no Indian Standards exist,

formulators/marketers may be responsible to lay down their own standards and comply with the same.

4 Herb(s)/Herbal Ingredient(s)

The 'herb(s)/herbal ingredient(s)' for use in products covered under these guidelines, shall mean to include one or more of the following:

- a) Fresh herbs/juices/pastes/oleoresins made from whole or part(s) of plants,
- b) Dried powdered herbs,
- c) Herbal extracts,
- d) Cold expressed and/or solvent extracted, fixed oils/fats from herbs, and
- e) Distillates/Essential oils of herbs.

5 SELECTION OF HERB

5.1 Selection of Herbal Ingredients

Formulators should carefully select herbs/herbal ingredients based on their known and reported properties (in literature), properties known in cultural heritage or traditional use and usage reported in traditional books. Formulators shall also apply adequate care in selecting the forms in which the herbs would be used as an 'ingredient' in the products. Formulators may use an herbal ingredient for newer uses than known earlier provided; adequate data is available on that ingredient and its newer use.

6 QUANTITY/ PROPORTIONS OF HERBS USED

Formulators should have adequate data justifying the proportion of the herbs or the herbal ingredient(s) for which claims are made, used in the product. In the absence of scientific data, availability of the quantity of herb in a product to provide the intended cosmetic benefits, such data may be based on the known knowledge, published literature, and reported knowledge in traditional books and/or scientifically generated data using appropriate *in-vitro* and/or *in-vivo* (clinical) methods.

7 HERBAL COSMETIC BENEFITS CLAIMS

The cosmetic benefit claims made for products shall be true, factual and based on the data in possession with the formulators/marketers. Such data may be based on the known knowledge, published literature, knowledge reported in traditional books and/or scientifically generated data using appropriate *in-vitro* and/or *in-vivo* (clinical) methods. No formulators/marketers shall make

any cosmetic claim/claims, which are false, exaggerated or misleading. However, in cases where cosmetic benefit claims are linked specifically to herbs/herbal ingredients, the formulator/marketer shall do so, based on adequate and appropriate data in their possession justifying that the particular benefit claim is actually provided by the herb/herbal ingredients.

Formulators/marketers who are incorporating herbal ingredient(s) for varianting purposes shall ensure any cosmetic benefit claim made shall be delivered by the product as a whole, even though such benefits are not attributable to any specific herbal ingredient, and such cosmetics shall be governed by the current regulations under *D&C Act* and *Rules* as applicable to cosmetics. However, no formulator/marketers shall make any cosmetic benefit claim, which is not delivered by the product.

8 QUALITY ASSURANCE

It is recognized that testing of herbal ingredients in herbal cosmetics is not easy and practicable due the multi-component nature of herbal ingredients. Formulators using herb/herbal ingredients shall adopt necessary quality assurance techniques while deciding to use an herb/herbal ingredient. Adequate raw material quality control shall be adopted each time when a herb/herbal ingredient is used. Use of herb/herbal ingredients shall be done through 'Certification by addition' during manufacturing and such certification documentation shall be recorded and maintained in the relevant 'Master product specification' or 'Bill of materials' or 'Weighment sheet' duly authenticated by the production and quality personnel. Written procedures would be available for it and records shall be maintained for having applied the procedures and their results of compliance.

9 SHELF-LIFE DATA

Formulators may adopt suitable shelf-life study protocols which ensure product integrity throughout the intended shelf-life period through appropriate data. Visible signs of degradation such as fermentation, rancidity, change in colour, and such other parameters as applicable to the product shall be used to prove the stability of the product.

Samples of the products exposed to pre-decided challenge conditions of storage shall also be tested for confirming the claimed cosmetics benefits. Finger printing technique or any other suitable methods would be acceptable while generating shelf-life data. Stability of herbal ingredient(s) proven in a cosmetics formulation base can be justified and extrapolated to cosmetics with similar base formulation with changes within normal ranges from proven product.

10 SAFETY DATA

Formulators shall ensure that the finished product is safe (*see* IS 4011). Results of safety data/such studies should be available with the formulators/marketers and shall be produced, whenever required.

Formulators/marketers shall suitably inform the consumer, if there are any precautions to be taken while using the products, which are known to show safety concerns in specific individual/population on the labels of such products.

For microbiological evaluation/examination, reference may be made to IS 14648. For the purpose of hygienic manufacture of cosmetics, reference may be made to IS 11377 and for sampling details, reference may be made to IS 3958.

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Amendments Issued Since Publication

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